

IN, THE CLAIMS

Please cancel Claims 1 – 150 without prejudice or disclaimer. Please add claims 151 – 214 as shown below. This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1 – 150. (Cancelled).

Claim 151. (New) An orally deliverable pharmaceutical composition, comprising: at least one acid labile substituted benzimidazole H⁺, K⁺- ATPase proton pump inhibitor in a therapeutically effective amount and at least one buffering agent, wherein:

- (a) the composition is in a form of a solid dosage unit; and
- (b) upon oral administration of the composition to a plurality of subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml at any time within about 30 minutes after administration.

Claim 152. (New) The composition of claim 151, wherein the dosage unit is selected from the group consisting of a tablet, a capsule, a powder, a suspension tablet, a chewable tablet, an effervescent tablet, a troche and a lozenge.

Claim 153. (New) The composition of claim 151, wherein the dosage unit is selected from the group consisting of a tablet, a chewable tablet and a capsule.

Claim 154. (New) The composition of claim 151, wherein at least a portion of the at least one proton pump inhibitor is enteric coated.

Claim 155. (New) The composition of claim 151, wherein the at least one proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 156. (New) The composition of claim 155, wherein the at least one proton pump inhibitor is present in the composition in an amount of about 1 mg to about 1000 mg.

Claim 157. (New) The composition of claim 155, wherein the at least one proton pump inhibitor is present in the composition in an amount of about 5 mg to about 300 mg.

Claim 158. (New) The composition of claim 155, wherein the at least one proton pump inhibitor is present in the composition in an amount of about 10 mg to about 100 mg.

Claim 159. (New) The composition of claim 155, wherein the at least one proton pump inhibitor is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 40 mg, about 50 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110mg, about 115 mg, about 120 mg, about 150 mg, about 200 mg, about 250 mg, or about 300 mg.

Claim 160. (New) The composition of claim 155, wherein the at least one proton pump inhibitor is omeprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 161. (New) The composition of claim 151, wherein the at least one proton pump inhibitor is lansoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 162. (New) The composition of claim 151, wherein the at least one proton pump inhibitor is esomeprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 163. (New) The composition of claim 151, further comprising at least one pharmaceutically acceptable excipient selected from the group consisting of a carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, an isotonic agent, and mixtures thereof.

Claim 164. (New) The composition of claim 151, wherein the at least one buffering agent is selected from the group consisting of calcium buffering agents, magnesium buffering agents, aluminum buffering agents, sodium buffering agents, bicarbonate salts of a Group IA metal, alkali earth metal buffering agents, and mixtures thereof.

Claim 165. (New) The composition of claim 151, wherein the at least one buffering agent is selected from the group consisting of sodium bicarbonate, potassium bicarbonate,

magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, potassium phosphate, sodium phosphate, and mixtures thereof.

Claim 166. (New) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 1 mEq to about 200 mEq.

Claim 167. (New) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 3 mEq to about 45 mEq.

Claim 168. (New) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 4 mEq to about 100 mEq.

Claim 169. (New) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 4 mEq to about 30 mEq.

Claim 170. (New) The composition of claim 151, wherein the at least one buffering agent is present in the composition in a total amount of about 10 mEq to about 70 mEq.

Claim 171. (New) The composition of claim 151, wherein the at least one buffering agents comprises sodium bicarbonate.

Claim 172. (New) The composition of claim 171 wherein the sodium bicarbonate is present in the composition in a total amount of about 250 mg to about 4000 mg.

Claim 173. (New) The composition of claim 171 wherein the sodium bicarbonate is present in the composition in a total amount of about 1000 mg to about 1680 mg.

Claim 174. (New) The composition of claim 171 wherein the sodium bicarbonate is present in the composition in a total amount of about 20 mEq.

Claim 175. (New) The composition of claim 174 wherein the at least one proton pump inhibitor is omeprazole and said omeprazole is present in the composition in an amount of about 20 mg.

Claim 176. (New) The composition of claim 174 wherein the at least one proton pump inhibitor is omeprazole and said omeprazole is present in the composition in an amount of about 40 mg.

Claim 177. (New) The composition of claim 151, wherein the at least one buffering agent comprises magnesium hydroxide.

Claim 178. (New) The composition of claim 177, wherein the magnesium hydroxide is present in the composition in a total amount of about 12 mEq to about 24 mEq.

Claim 179. (New) The composition of claim 151, wherein the at least one buffering agent comprises a mixture of sodium bicarbonate and magnesium hydroxide.

Claim 180. (New) The composition of claim 151, wherein the at least one buffering agent comprises calcium carbonate.

Claim 181. (New) The composition of claim 151, wherein the at least one buffering agent comprises a mixture of sodium bicarbonate and calcium carbonate.

Claim 182. (New) The composition of claim 151, wherein at least a portion of the at least one proton pump inhibitor is micronized.

Claim 183. (New) The composition of claim 151, wherein at least a portion of the at least one buffering agent is micronized.

Claim 184. (New) The composition of claim 151, wherein the solid dosage unit is non-enteric coated.

Claim 185. (New) The composition of claim 151, wherein upon oral administration of the composition to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml at any time within about 20 minutes after administration.

Claim 186. (New) The composition of claim 151, wherein upon oral administration of the composition to a plurality of fasted adult human subjects, the subjects exhibit an average

plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 187. (New) The composition of claim 151, wherein upon oral administration of the composition to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml at any time within about 10 minutes after administration.

Claim 188. (New) The composition of claim 151, wherein upon oral administration of the composition to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.2 µg/ml at any time within about 15 minutes after administration.

Claim 189. (New) The composition of claim 151, wherein upon oral administration of the composition to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 6 hours after administration.

Claim 190. (New) The composition of claim 151, wherein upon oral administration of the composition to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.15 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 1.5 hours after administration.

Claim 191. (New) An orally deliverable pharmaceutical composition, comprising: omeprazole or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof, in a therapeutically effective amount and at least one buffering agent, wherein:

- (a) the composition is in a form of a solid dosage unit; and
- (b) upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml at any time within about 30 minutes after administration.

Claim 192. (New) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a plurality of fasted adult

human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 20 minutes after administration.

Claim 193. (New) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 194. (New) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml at any time within about 10 minutes after administration.

Claim 195. (New) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.2 µg/ml at any time within about 15 minutes after administration.

Claim 196. (New) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.1 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 6 hours after administration.

Claim 197. (New) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a plurality of fasted adult human subjects, the subjects exhibit an average plasma concentration of the proton pump inhibitor of at least about 0.15 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 1.5 hours after administration.

Claim 198. (New) The composition of claim 191, wherein the dosage unit is selected from the group consisting of a tablet, a capsule, powder, a suspension tablet, a chewable tablet, a lozenge, an effervescent tablet, and a troche.

Claim 199. (New) The composition of claim 191, wherein the dosage unit is selected from the group consisting of a tablet, a chewable tablet, and a capsule.

Claim 200. (New) The composition of claim 191, further comprising at least one pharmaceutically acceptable excipient selected from the group consisting of a carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, an isotonic agent, and mixtures thereof.

Claim 201. (New) The composition of claim 191, wherein the at least one buffering agent is selected from the group consisting of calcium buffering agents, magnesium buffering agents, aluminum buffering agents, sodium buffering agents, bicarbonate salts of a Group IA metal, alkali earth metal buffering agents, and mixtures thereof.

Claim 202. (New) The composition of claim 191, wherein the at least one buffering agent is selected from the group consisting of sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, potassium phosphate, sodium phosphate, and mixtures thereof.

Claim 203. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 1 mEq to about 200 mEq.

Claim 204. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 3 mEq to about 45 mEq.

Claim 205. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 4 mEq to about 100 mEq.

Claim 206. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 4 mEq to about 30 mEq.

Claim 207. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 10 mEq to about 70 mEq.

Claim 208. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 3 mEq.

Claim 209. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 10 mEq.

Claim 210. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 20 mEq.

Claim 211. (New) The composition of claim 191, wherein the at least one buffering agent is present in the composition in a total amount of about 40 mEq.

Claim 212. (New) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 1 mg to about 1000 mg.

Claim 213. (New) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 5 mg to about 300 mg.

Claim 214. (New) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 10 mg to about 100 mg.